(5)

No. 98-1109

In the Supreme Court of the United States

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL., PETITIONERS

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

JOINT APPENDIX

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PETITION FOR WRIT OF CERTIORARI FILED: JANUARY 11, 1999
CERTIORARI GRANTED: APRIL 19, 1999

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

No. 96 C 2953
Judge Lindberg

THE ILLINOIS COUNCIL ON LONG TERM CARE INC., AN ILLINOIS CORPORATION, PLAINTIFF-APPELLANT

vs.

DONNA E. SHALALA, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ANTHONY J. TIRONE, IN HIS CAPACITY AS DEPUTY DIRECTOR OF THE UNITED STATES OFFICE OF SURVEY AND CERTIFICATION, HEALTH STANDARDS AND QUALITY BUREAU, HEALTH CARE FINANCING ADMINISTRATION; AND JOHN R. LUMPKIN M.D., AS DIRECTOR OF THE ILLINOIS DEPARTMENT OF PUBLIC HEALTH, DEFENDANTS-APPELLEES

DOCKET ENTRIES

DATE	DOCKET NUMBERS	PROCEEDINGS
5/17/96	1	COMPLAINT - Civil cover sheet - Appearance(s) of Brian E. Neuffer, Dan K. Webb, John Norman Walker, Charles Paul

DATE	DOCKET NUMBERS	PROCEEDINGS
		Sheets, Neil E. Holmen as attorney(s) for plaintiff with Rule 39 affidavits (FIVE ORIGINAL summons(es) issued.) (Documents: 1-1 through 1-9) (dk) [Entry date 05/20/96]
		* * * * *
6/12/96	8	AMENDED COMPLAINT [1-1] by plaintiff (Exhibits). (dk) [Entry date 06/13/96]
		* * * * *
7/30/96	12	MOTION by federal defendants to dismiss or, in the alternative, for summary judgment (Attachment). (dk) [Entry date 08/05/96]
8/1/96	13	STATEMENT of material facts as to which there is no genuine issues by defendants (dk) [Entry date 08/05/96]
8/1/96	14	BRIEF by federal defendants in support of motion to dismiss [13-1], or, in the alternative, for summary judgment [13-2] (Exhibits). (dk) [Entry date 08/05/96]

DATE	DOCKET NUMBERS	PROCEEDINGS
8/1/96	15	MINUTE ORDER of 8/1/96 by Hon. George W. Lindberg: Response to federal defendants' motion to dismiss [13-1], or in the alternative, for summary judgment due 08/23/96 [13-2]. Reply due 08/30/96. Federal defendants' motion to file a brief in excess of 15 pages [11-1] is granted. Ruling set for 09/26/96 at 9:30 a.m. Mailed notice (dk) [Entry date 08/05/96]
		* * * * *
8/14/96	19	MOTION by plaintiff for preliminary injunction. (dk) [Entry date 08/15/96]
		* * * * *
10/4/96	24	MEMORANDUM by plaintiff in support of motion for preliminary injunction [19-1] with opposition (Exhibits). (dk) [Entry date 10/07/96]
10/4/96	24	OPPOSITION by plaintiff to motion to dismiss [13-1], or in the alternative for for summary judgment [13-2] with memorandum (Exhibits). (dk) [Entry date 10/07/96]

DATE	DOCKET NUMBERS	PROCEEDINGS
10/4/96	25	RESPONSE to Federal defendant's statement of material facts to which there is no genuine dispute by plaintiff (Exhibits). (dk) [Entry date 10/07/96]
		* * * * *
10/22/96	26	AMICUS CURIAE BRIEF by Amer Hlth Care Assn in opposition to defendants' motion to dismiss [13-1], or in the alternative, for summary judgment [13-2] (dk) [Entry date 10/24/96]
		* * * * *
11/8/96	29	REPLY by defendants to plaintiff's opposition to federal defendants' motion to dismiss [13-1] with motion. (dk) [Entry date 11/19/96]
11/8/96	30	BRIEF by defendant in opposition to plaintiff's motion for preliminary injunction [19-1] with reply (Attachments). (dk) [Entry date 11/19/96]
11/8/96	30	REPLY by defendants to plaintiff's opposition to federal defendants' motion to dismiss [13-1]

DATE	DOCKET NUMBERS	PROCEEDINGS
		with brief (Attachments). (dk) [Entry date 11/19/96]
11/8/96	31	REPLY by federal defendants to plaintiff's response to federal defendants' statement of material facts to which there is no genuine dispute [25-1]. (dk) [Entry date 11/19/96]
11/8/96	32	MOTION by unknown Natl Citizens to file an amicus brief; Notice of motion and proof of service. (dk) [Entry date 11/19/96]
11/18/96	33	MINUTE ORDER of 11/18/96 by Hon. George W. Lindberg: Motion of the National Citizens' Coalition for Nursing Home Reform to file an amicus brief [32-1] is granted. * * * [Entry date 11/19/96]
11/18/96	34	BRIEF amicus curiae by The National Citizens' Coalition for Nursing Home Reform (Exhibits). (dk) [Entry date 11/19/96]
		* * * * *

DATE	DOCKET NUMBERS	PROCEEDINGS
12/6/96	37	REPLY memorandum by plaintiff in support of its motion for preliminary injunction [19-1] (Attachment). (dk) [Entry date 12/09/96]
1/8/97	–	SCHEDULE set on 1/8/97 by Hon. George W. Lindberg: Oral argument on defendant's motion to dismiss and the motion for preliminary injunction set for January 31, 1997 at 10:30 a.m. Mailed notice (sab)
		* * * * *
3/28/97	40	MEMORANDUM AND ORDER (dk) [Entry date 03/31/97]
3/28/97	41	MINUTE ORDER of 3/28/97 by Hon. George W. Lindberg: Defendants' motion to dismiss [13-1] is granted. Defendants' motion for summary judgment [13-2] is denied as moot. Plaintiff's motion for preliminary injunction [19-1] is denied as moot. Motion for summary judgment [27-2] is moot. Enter memorandum and order terminating case. Mailed notice (dk) [Entry date 03/31/97]

DATE	DOCKET NUMBERS	PROCEEDINGS
3/28/97	42	ENTERED JUDGMENT (dk) [Entry date 03/31/97]
5/23/97	43	TRANSCRIPT of proceedings for the following date(s): 01/31/97 Before Honorable George W. Lindberg (eav) [Entry date 05/27/97]
5/27/97	44	NOTICE OF APPEAL by plaintiff IL Coun Long Term from judgment entered [42-1], from Scheduling order terminating case [41-1], from motion minute order [41-2], from order [40-1] ($105.00 Paid) (cmf) [Entry date 05/30/97]
5/27/97	45	DOCKETING STATEMENT by plaintiff IL Coun Long Term regarding appeal [44-1]. (cmf) [Entry date 05/30/97]
5/30/97	–	TRANSMITTED to the 7th Circuit the short record on appeal. Mailed notice to all counsel. (cmf)
6/9/97	–	TRANSMITTED to the 7th Circuit the long record on

DATE	DOCKET NUMBERS	PROCEEDINGS
		appeal no. consisting one volume of pleading , two volumes of loose pleadings (item # 1-1 & 30), three volumes of exhbits (item # 8, 14, & 24) , one volume of transcript (item # 43) of Mailed notice to all counsel. (da)
6/24/97	46	SEVENTH CIRCUIT transcript information sheet by plaintiff (eav) [Entry date 06/25/97]
8/18/98	47	CERTIFIED copy of Order from the Circuit. (97-2315); The petition for rehearing is therefore denied, and the suggestion for rehearing en banc is rejected. (ip) [Entry date 08/25/98]
8/21/98	48	CERTIFIED copy of Order from the Circuit. (97-2315); The petition for rehearing is therefore denied, and the suggestion for rehearing en banc is rejected. (ip) [Entry date 08/26/98]
8/21/98	49	CERTIFIED COPY of order from the 7th Circuit: Remanding the matter back to District Court [Appeal [44-1].

DATE	DOCKET NUMBERS	PROCEEDINGS
		(97-2315) (ip) [Entry date 08/26/98]
8/21/98	50	OPINION from the 7th Circuit: Argued 12/5/97; Decided 5/8/98. (97-2315) (ip) [Entry date 08/26/98]
8/21/98	51	LETTER from the 7th Circuit: Retaining record on appeal no. 97-2315 consisting of 1 volume of pleadings, 2 loose pleadings, 1 volume transcripts and volume of exhibits (Attachments) (ip) [Entry date 08/26/98]
9/4/98	52	LETTER from the 7th Circuit returning the record on appeal no. 97-2315 consisting of 1 volume of pleadings, 2 loose pleadings, 1 volume of transcripts and 3 volumes of exhibits (eav) [Entry date 09/08/98]
		* * * * *
4/28/99	–	SCHEDULE set on 4/28/99 by Hon. George W. Lindberg: Status hearing held and continued to April 27, 2000 at 9:30a.m. No notice (sab)

UNITED STATES COURT OF APPEALS FOR
THE SEVENTH CIRCUIT

No. 97-2315

THE ILLINOIS COUNCIL ON LONG TERM CARE INC., AN ILLINOIS CORPORATION, PLAINTIFF-APPELLANT

vs.

DONNA E. SHALALA, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ANTHONY J. TIRONE, IN HIS CAPACITY AS DEPUTY DIRECTOR OF THE UNITED STATES OFFICE OF SURVEY AND CERTIFICATION, HEALTH STANDARDS AND QUALITY BUREAU, HEALTH CARE FINANCING ADMINISTRATION; AND JOHN R. LUMPKIN, AS DIRECTOR OF THE ILLINOIS DEPARTMENT OF PUBLIC HEALTH, DEFENDANTS-APPELLEES

GENERAL DOCKET ENTRIES

DATE	PROCEEDINGS
6/2/97	U.S. civil case docketed. [97-2315] [954320-1] Transcript information sheet due 6/12/97. Appellant's brief due 7/14/97 for IL Council Long Term. (dorh)
6/2/97	[97-2315] ROA from No. Dist. of Il., E. Div. due 6/10/97. (dorh)

DATE	PROCEEDINGS
6/2/97	Filed Appellant IL Council Long Term docketing statement. [97-2315] [954344-1] (dorh)
6/11/97	Original record on appeal filed. Contents of record: 1 vol. pleadings; 1 vol. transcripts; 2 vol. loose pleadings; 3 vol. exhibits; . [97-2315] [956310-1] (fran)
	* * * * *
8/6/97	Filed 15c appellant's brief by IL Council Long Term. Disk filed. [97-2315] [974729-1] (kell)
8/6/97	Added attorney Pamela Small per appearance form. Appearance form filed for Notice-Only by attorney Pamela B. Small, Malcolm J. Harkins. [97-2315] [954320-1] (jenp)
	* * * * *
8/6/97	Filed 15c amicus brief by Amicus Curiae American Health Care, per order. Disk filed. [97-2315] [977449-1] (heid)
	* * * * *
9/24/97	Filed 15c appellees' brief by Donna E. Shalala and Anthony J. Tirone. Disk filed. [97-2315] [990838-1] (heid)

DATE	PROCEEDINGS
9/24/97	Filed 15c appellee's brief by John R. Lumpkin. Certification filed. [97-2315] [991472-1] (heid)
10/8/97	Filed 15c appellant's reply brief by IL Council Long Term. Disk filed. [97-2315] [995602-1] (heid)
10/10/97	Filed Appellant IL Council Long Term Citation of Additional Authority, per CR 28(j). [97-2315] [996419-1] (joce)
10/17/97	ORDER: Argument set for Friday, December 5, 1997 at 9:30 a.m. 20 minutes to appellants, 10 minutes to Illinois, 10 minutes to USA. [97-2315] [997483-1] (broo)
12/5/97	Case heard and taken under advisement by panel: Circuit Judge Frank H. Easterbrook, Circuit Judge Diane P. Wood, Circuit Judge Terence T. Evans. [97-2315] [1013435-1] (broo)
12/5/97	Case argued by James C. O'Connell for Appellee John R. Lumpkin, Jeffrey Clair for Appellee Anthony J. Tirone, Appellee Donna E. Shalala, Brian E. Neuffer for Appellant IL Council Long Term. [97-2315] [954320-1] (broo)

DATE	PROCEEDINGS
12/9/97	Attorney Brian E. Neuffer added for Appellant IL Council Long Term for purposes of oral argument. [97-2315] (broo)
1/26/98	Filed Appellee Donna E. Shalala, Appellee Anthony J. Tirone Citation of Additional Authority, per CR 28(e). Dist. [97-2315] [1027349-1] (land)
5/8/98	Filed opinion of the court by Easterbrook. VACATED and REMANDED for further proceedings. Circuit Judge Frank H. Easterbrook, Circuit Judge Diane P. Wood, Circuit Judge Terence T. Evans. [97-2315] [954320-1] (orac)
5/8/98	ORDER: Final judgment filed per opinion. With costs: n. [97-2315] [1060445-1] (orac)
6/22/98	Filed 30c Petition for Rehearing with Suggestion for Rehearing Enbanc by Appellee Donna E. Shalala, Appellee Anthony J. Tirone, Appellee John R. Lumpkin. Dist. [97-2315] [1074089-1] (kell)
6/29/98	Sent clerk's copy of request to Appellant IL Council Long Term requesting 30c of their Answer to the Petition for Rehearing with Suggestion for Rehearing Enbanc filed by the Appellees on 6/22/98. [97-2315] [1076077-

DATE	PROCEEDINGS
	1] Answer to Petition for Enbanc Rehearing due 7/13/98 for IL Council Long Term. (jame)
7/13/98	Filed 30c Answer of Appellant IL Council Long Term to Petition for Rehearing with Suggestion for Rehearing Enbanc. Dist. [97-2315] [1080284-1] (kell)
8/13/98	ORDER: Appellee Donna E. Shalala, Appellee Anthony J. Tirone, Appellee John R. Lumpkin Petition for Rehearing with Suggestion for Rehearing Enbanc is DENIED. Judge Flaum did not participate in the consideration of the suggestion for rehearing en banc. Judges Ripple, Manion and Rovner voted to grant rehearing en banc. [97-2315] [1074089-1] (kell)
8/21/98	MANDATE ISSUED. Record on appeal to be returned later. (Contents to be returned: 1 vol. pleadings; 2 vol. loose pleadings; 1 vol. transcripts; 3 vol. exhibits;.) [97-2315] [954320-1] (bobi)
8/25/98	Filed mandate receipt. [97-2315] [1093733-1] (fran)
9/3/98	Original record returned to the District Court. (Contents returned: 1 vol. pleadings; 2 vol. loose pleadings; 1 vol. transcripts; 3 vol. exhibits;.) [97-2315] [954320-1] (odea)

DATE	PROCEEDINGS
9/28/98	Filed record receipt. [1103721-1] [97-2315] (fran)
11/9/98	Notice from the Supreme Court that a motion for extension of time to file a Petition for Writ of Certiorari has been GRANTED, extending such time to 12/12/98. [954320-1] [97-2315] (land)
12/8/98	Notice from the Supreme Court that a motion for extension of time to file a Petition for Writ of Certiorari has been GRANTED, extending such time to 1/10/99. [954320-1] [97-2315] (heid)
1/15/99	Filed notice from the Supreme Court of the filing of a Petition for Writ of Certiorari. Supreme Court Case No.: 98-1109. [97-2315] [1138109-1] (jame)
4/22/99	Filed order from the Supreme Court GRANTING the Petition for Writ of Certiorari. Supreme Court Case No.: 98-1109. [97-2315] [1170690-1] (heid)
4/22/99	Filed order from the Supreme Court DENYING the Petition for Writ of Certiorari. Supreme Court Case No.: 98-1307. [97-2315] [1171109-1] (squi)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

No. 96 C 2953
Judge Lindberg

THE ILLINOIS COUNCIL ON LONG TERM CARE INC., AN ILLINOIS CORPORATION, PLAINTIFF

vs.

DONNA E. SHALALA, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ANTHONY J. TIRONE, IN HIS CAPACITY AS DEPUTY DIRECTOR OF THE UNITED STATES OFFICE OF SURVEY AND CERTIFICATION, HEALTH STANDARDS AND QUALITY BUREAU, HEALTH CARE FINANCING ADMINISTRATION; AND JOHN R. LUMPKIN M.D., AS DIRECTOR OF THE ILLINOIS DEPARTMENT OF PUBLIC HEALTH, DEFENDANTS

AMENDED COMPLAINT

Plaintiff, The Illinois Council on Long-Term Care, complains against Defendant Donna E. Shalala, Secretary of the United States Department of Health and Human Resources ("HHS"), Defendant Anthony J. Tirone, Deputy Director of the United States Office of Survey and Certification, Health Standards and Quality Bureau, Health Care Financing Administration ("HCFA"), and Defendant John R. Lumpkin M.D., Director of the Illinois Department of Public Health ("IDPH"), as follows:

NATURE OF THE ACTION

1. In this case, Plaintiff does not seek to overturn or modify the new health, safety, and resident rights standards established by the Omnibus Budget Reconciliation Act of 1987 ("OBRA 87"), known as the "Requirements of Participation" pertaining to the Medicaid and Medicare Programs. Indeed, Plaintiff's members have been surveyed for compliance with the Requirements of Participation since their promulgation in November, 1990, and only about 6% of them have been found out of compliance.

2. Plaintiff seeks, on behalf of its members participating in Medicaid (Counts I-III) and those participating in Medicare (Counts IV-VII), declaratory and injunctive relief, pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. The relief sought is only against the use of certain unconstitutionally vague HCFA enforcement regulations which took effect on July 1, 1995 (the "1995 Regulations"), and certain standards and protocols informally promulgated thereunder in Transmittals 273 and 274, State Operations Manual (the "*SOM*"). The 1995 Regulations and the SOM have permitted arbitrary and inconsistent enforcement of the Requirements of Participation by Defendants, while simultaneously immunizing their actions from meaningful challenge by Plaintiff's members, in violation of due process of law. As a result of Defendants' conduct, the proportion of Plaintiff's members found to be out of compliance with the Requirements of Participation has soared from 6% to over 70% in the last ten months, even though the underlying Requirements of Participation have not changed.

3. Plaintiff seeks a declaratory judgment to the effect that:

A. The enforcement regulations promulgated by HCFA, which became effective on July 1, 1995 (the "1995 Regulations"), the SOM, and the various informal modifications thereof violate the Administrative Procedure Act in that they deviate from and exceed the mandate of the Omnibus Budget Reconciliation Act of 1987 ("OBRA '87") and, in the case of the SOM and informal modifications, were promulgated without the required notice and comment procedures required by the Administrative Procedures Act for substantive regulations;

B. The 1995 Regulations and the SOM are too vague and leave too many terms undefined to permit Plaintiff's members fair warning as to what conduct is proscribed and to permit surveyors sufficient guidance to fairly and consistently assess the compliance of nursing facilities;

C. The 1995 Regulations and the SOM have been inconsistently enforced, in violation of the Social Security Act;

D. The administrative review procedures provided under the 1995 Regulations violate Plaintiff's members' rights to procedural due process, because: (1) they are not permitted a pre-deprivation hearing before the imposition of even the most severe remedies such as termination, only a post deprivation hearing that can occur months after deprivation; (2) the Plaintiff's members are prohibited from contesting the crucial "scope"

and "severity" assessments of the surveyors in any post-deprivation hearings that are provided; and (3) the regulatory scheme is designed to provide Plaintiff's members with less and less process as termination approaches.

E. The remedies mandated by the regulations expose Plaintiff's members to actual and threatened irreparable harm in violation of their statutory rights and their constitutional rights to due process of law.

4. Plaintiff also seeks, first preliminarily and then permanently, an injunction against Defendants from enforcing the 1995 Regulations or the SOM against any of Plaintiff's nursing facility members.

PARTIES

5. Plaintiff is a not-for-profit trade association, duly organized and existing under the Illinois Not For Profit Corporation Act. Plaintiff's membership is comprised of more than 180 nursing facilities in Illinois.

6. Approximately 75 of Plaintiffs' members participate in only the Medicaid program, and not Medicare (hereafter "Medicaid-Only" members). Under the Medicaid program, Plaintiffs' members provide long term care to approximately 24,000 indigent persons pursuant to provider agreements with the Illinois Department of Public Aid ("IDPA"). The Plaintiff's claims on behalf of its Medicaid-Only members are set forth in Counts I-III below. Plaintiffs' remaining members (approximately 105) participate jointly in Medicare and Medicaid (hereafter "Medicare" members). Under the Medicare program, these members provide long

term care to approximately 5,000 aged persons pursuant to provider agreements with the Defendant Secretary of HHS. The Plaintiff's claims on behalf of the Medicare members are set forth in Counts IV-VII below.

7. Each of Plaintiff's members either has been or will be inspected, or "surveyed", for certification to continue under their provider agreements by Defendant IDPH, pursuant to the 1995 Regulations and the SOM. Plaintiff therefore has standing to bring this action because each of its individual members would have such standing, the interests Plaintiff seeks to protect are related to its organizational goals, and the claims asserted do not require the participation of each of its members.

8. Defendant Donna E. Shalala is the Secretary of HHS. HHS is responsible for the administration of the Medicare program under Title XVIII of the Social Security Act and the Medicaid program under Title XIX of the Social Security Act. Defendant, as the Secretary of HHS, promulgated the 1995 Regulations.

9. Defendant Anthony J. Tirone is the Deputy Director of HCFA. HCFA has the direct responsibility for supervising the implementation of the Medicare and Medicaid programs. HCFA issued the SOM, and supervises the implementation of the 1995 Regulations and the SOM.

10. Defendant John R. Lumpkin M.D. is the Director of IDPH. IDPH is responsible for applying the 1995 Regulations and the SOM to nursing facilities in Illinois.

SUBJECT MATTER JURISDICTION AND VENUE REGARDING CLAIMS ON BEHALF OF MEDICAID-ONLY MEMBERS

11. Plaintiff's claims on behalf of its Medicaid-Only members arise under the Fifth and Fourteenth Amendments to the United States Constitution, the provisions of the Social Security Act pertaining to Medicaid, 42 U.S.C. § 1396 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. §553 *et seq.* Plaintiff seeks declaratory judgment, as well as preliminary and permanent injunctions against the Defendants. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. §§ 1331, 1346 and 2201.

12. Plaintiff's claims on behalf of its Medicaid-Only members arise out of acts undertaken and injuries suffered in this district. Venue is proper pursuant to 28 U.S.C. § 1391.

13. This Court has jurisdiction over Plaintiff's claims on behalf of its Medicaid-Only members, without regard to exhaustion of administrative remedies, because Plaintiff does not challenge the specific application of the 1995 Regulations and the SOM to any one facility, but challenges instead their lawfulness and their use to determine alleged certification deficiencies and impose enforcement penalties. Administrative review is unavailable to Plaintiff's members because the 1995 Regulations and the SOM preclude administrative review of those aspects of the 1995 Regulations and the SOM that Plaintiff alleges are unlawful.

SUBJECT MATTER JURISDICTION AND VENUE REGARDING CLAIMS ON BEHALF OF MEDICARE MEMBERS

14. Plaintiff's claims on behalf of its Medicare members arise under the Fifth and Fourteenth Amendments to the United States Constitution, the provisions of the Social Security Act pertaining to Medicare, 42 U.S.C. § 1395 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. §553 *et seq.* Plaintiff seeks declaratory judgment, as well as preliminary and permanent injunctions against the Defendants. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. §§ 1331, 1346 and 2201.

15. Plaintiff's claims on behalf of its Medicare members arise out of acts undertaken and injuries suffered in this district. Venue is proper pursuant to 28 U.S.C. § 1391.

16. This Court has jurisdiction over Plaintiff's claims on behalf of its Medicare members, without regard to exhaustion of administrative remedies, because Plaintiff does not challenge the specific application of the 1995 Regulations and the SOM to any one facility, but challenges instead their lawfulness and their use to determine alleged certification deficiencies and impose enforcement penalties. Administrative review is unavailable to Plaintiff's members because the 1995 Regulations and the SOM specifically preclude administrative review of those aspects of the 1995 Regulations and the SOM that Plaintiff alleges are unlawful.

FACTUAL ALLEGATIONS

17. There are presently approximately 776 nursing facilities in Illinois that are certified and have provider agreements with HHS and the IDPA to provide services under the Medicare and/or Medicaid programs. These nursing facilities provide care to approximately 55,000 eligible indigent residents who are receiving Medicaid and 7,000 eligible aged residents who are receiving Medicare. These nursing facilities collectively have an investment of approximately three billion dollars ($3,000,000,000.00) in buildings and equipment.

A. The Medicaid Program

18. The Social Security Act provides for health care services for individuals whose income and resources are below certain amounts ("indigent persons") under the Medicaid program. 42 U.S.C. § 1396 *et seq.*

19. Under the Medicaid program, a state develops a plan in conjunction with the federal government for a system of benefits for indigent persons and, if the plan meets certain requirements, the federal government pays up to 50% of the cost of the benefits. The IDPA enters into provider agreements with nursing facilities to provide the services under Medicaid.

20. The Social Security Act establishes certain health, safety and resident rights standards, known as "Requirements of Participation", that a nursing facility must meet to be certified to enter into Medicaid provider agreements. 42 U.S.C. § 1396r(a)(3), (b)-(d). Nursing facilities that enter into provider agreements must be annually certified as meeting these same

Requirements of Participation in order to continue under their agreements. 42 U.S.C. § 1396r(b), (c).

21. The Social Security Act provides generally for surveys of nursing facilities and Medicaid provider agreements to determine whether they continue to meet the required health and safety standards. 42 U.S.C. 1396r(g). The surveys are to be conducted by a "State Survey Agency". In Illinois, the State Survey Agency is IDPH. IDPH surveys are conducted by approximately 230 IDPH employees and agents working out of nine regional offices, who are required to use "the survey methods, procedures, and forms that are prescribed by HCFA." 42 C.F.R. § 488.26(c).

22. The Social Security Act provides for the imposition of fines and other penalties, including termination of provider agreements, against nursing facilities found by the surveys to have failed to meet the Requirements of Participation. 42 U.S.C. § 1396r(g), (h). The penalties may be imposed by the State Survey Agency, IDPA, or by HHS.

23. IDPH is initially responsible for determining certification and implementing enforcement actions against most nursing facilities participating in Medicaid. HCFA and HHS retain ultimate authority for certification and enforcement actions under Medicaid.

B. The Medicare Program

24. The Social Security Act provides for health care services for individuals who are eligible for social security benefits ("aged persons") under the Medicare program. 42 U.S.C. §§ 426, 1395 *et seq.*

25. The Medicare program is administered and funded solely by the federal government, which enters directly into provider agreements with nursing facilities to provide services under the Medicare program.

26. The Social Security Act establishes certain health, safety and resident rights standards, known as "Requirements of Participation", that a nursing facility must meet to be certified to enter into Medicare provider agreements. 42 U.S.C. § 1395i-3(a)(3), (b)-(d). Nursing facilities that enter into provider agreements must be annually certified as meeting these same Requirements of Participation in order to continue under their agreements. 42 U.S.C. 1395i-3(b), (c). The standards are substantially the same for providers under both Medicare and Medicaid.

B. The Impact of OBRA '87

27. In 1987 the Social Security Act was amended by the Omnibus Budget Reconciliation Act of 1987 ("OBRA 87") in various ways, including changes in the health, safety and resident rights standards that make up the "Requirements of Participation." For enforcement of the Requirements of Participation, OBRA 87 added to the termination of provider agreements several new remedies, including: (1) civil monetary penalties ("CMPs") of up to $10,000 per day;

(2)imposition of temporary management; (3) appointment of a state monitor; and (4) denial of payments for new admissions; (5) directed Plans of Correction; and (6) directed in-service training. 42 U.S.C. 1395i-3(h) (Medicare); 42 U.S.C. 1396r(h) (Medicaid). OBRA 87 also mandated additional sanctions such as the loss of Nurse Aid Training and Competency Evaluation Programs ("NATCEP") 42 U.S.C. § 1395i-3(f)(2)(B) (Medicare); 42 U.S.C. § 1396r(f)(2)(B) (Medicaid), and the publication of adverse survey findings, such as notices of termination. 42 U.S.C. 1395i-3(g)(5) (Medicare); 42 U.S.C. 1396r(g)(5) (Medicaid).

28. HCFA published regulations concerning the Requirements of Participation on October 1, 1990, at 42 C.F.R. 483, Subparts E & F ("the 1990 Regulations").

29. From October 1, 1990 to July 1, 1995, the new Requirements of Participation were implemented and enforced by HCFA with the pre-OBRA 87 enforcement system. During this time period the number of facilities found not to be in compliance with the OBRA 87 requirements of participation averaged only 6% per year.

C. HCFA Violated The Administrative Procedure Act In Promulgating The Survey, Certification, and Enforcement Standards Contained In The 1995 Regulations And The State Operations Manual.

30. On November 10, 1994, HCFA published the final regulations concerning the survey, certification, and enforcement provisions of OBRA '87 (the "1995 Regulations"). These regulations, codified at 42 U.S.C. 488.300 *et seq.*, took effect on July 1, 1995.

31. The 1995 Regulations deviate substantially from the "Survey and Certification" and "Enforcement" mandates of OBRA '87, located at 1395r-3(g) & (h) for Medicare, and 1396r(g) & (h) for Medicaid. In particular, the 1995 Regulations:

A. legislate a set of detailed "scope" and "severity" classifications which are not called for in the statute, and which eliminate the State's discretion in assessing nursing facility deficiencies that was conferred by the statute.

B. remove the State's discretion to implement alternative remedies that was conferred by the statute.

C. restrict the standard of "substantial compliance" beyond what was contemplated by the statute, such that it is virtually impossible for the majority of nursing facilities to achieve or maintain "substantial compliance."

32. HCFA also issued a set of "informal regulations," known as Transmittals 273 and 274, State Operations Manual (the "SOM"), that became effective on July 1, 1995. The SOM changed both the survey protocol for inspecting a nursing facility and the basis for imposition of penalties, including termination of provider agreements. *See* Transmittals 273 and 274, SOM, attached hereto as Exhibit A.

33. The SOM is a substantive regulation that was not formally subjected to notice and comment procedures or promulgated as formal regulations. In particular, because the 1995 regulations created "scope"

and "severity" factors but failed to define them, HCFA requires IDPH to apply the "informal" definitions contained in the SOM to determine "substantial compliance" or "substandard quality of care."

34. The SOM also deviates from what was mandated by the 1995 Regulations and the Social Security Act. The SOM creates new concepts crucial to the enforcement scheme which are not defined or even mentioned in the 1995 regulations, such as "poor performing facilities," "historically compliant" and "date certain" facilities. SOM, §7001, 7304, 7313.

35. HCFA has made substantive changes to the *SOM* by way of satellite communications, written question-and-answer documents, and "interpretive" memoranda, none of which have been subjected to notice and comment procedures. For example, HCFA recently issued "reinterpretations" of the requirements for determining "substantial compliance" and "poorly performing facilities"[.] *See* HCFA Letter, dated December 6, 1995, at Exhibit B. These changes to the SOM were applied only prospectively. On information and belief, the requirements were altered again on or about January 26, 1996.

36. In its 1995 Regulations, HCFA effectively has exceeded the mandate of the statute and the 1990 Regulations thereunder. In promulgating the SOM and other "informal" mandates to State Survey Agencies, HCFA has further modified and expanded the 1995 Regulations without providing the formal notice and opportunity to comment required by the Administrative Procedure Act.

D. The Resulting HCFA Enforcement Regulations Are Impermissibly Vague, Inconsistently Applied, and Unreasonably Strict.

37. Under HCFA's current survey procedure, surveyors must first use the SOM to determine whether the facts indicate that deficiencies exist. A deficiency is any deviation from any Requirement of Participation.

38. Upon finding deficiencies, surveyors must use the SOM to assess whether each deficiency falls into one of the following "severity" categories: (1) "immediate jeopardy to resident health or safety;" (2) "actual harm that is not immediate jeopardy;" (3) "no actual harm with a potential for more than minimal harm, but not immediate jeopardy;" and (4) "no actual harm with a potential for minimal harm."

39. Surveyors must then use the SOM assess the "scope" of the deficiency as: (1) "Isolated;" (2) "Pattern;" or (3) "Widespread."

40. After deficiencies are collected and assessed, the surveyors must make certain determinations, including: (1) whether the deficiencies constitute a lack of "substantial compliance" with the Requirements of Participation overall; (2) whether the deficiencies constitute "substandard quality of care;" and (3) whether the deficiencies constitute "immediate jeopardy" to resident health or safety.

41. In Illinois, such determinations are made by the survey team and are documented. The IDPH makes these determinations without providing the facility any input or opportunity to respond. Moreover, the under-

lying documentation is not given to or discussed in any detail with the provider at the exit interview, but is mailed after the survey team leaves (usually within 10 days).

42. The survey process is virtually unbounded by the relevant statutory provisions, which fail to define certain key terms, including "compliance," "substantial compliance," "substandard quality of care" and "immediate jeopardy."

43. The 1995 Regulations define some of these terms, but many of these definitions are too vague and imprecise to provide meaningful guidance to surveyors and the providers. For example, 42 C.F.R. § 488.301 defines:

A. "substantial compliance" as "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." However, the term "minimal harm" is not defined;

B. "substandard quality of care" as "one or more deficiencies related to participation requirements" under the regulatory groupings entitled Resident Behavior and Facility Practices, 42 C.F.R. § 483.13, Quality of Life, 42 C.F.R. § 483.15, or Quality of Care, 42 C.F.R. § 483.25, which constitute (1) immediate jeopardy to resident health or safety, (2) a pattern of or widespread actual harm that is not immediate jeopardy, or (3) a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

44. These definitions are rendered vague in that the 1995 Regulations do not define many of the key terms contained therein, such as "actual harm," "minimal harm," "isolated," "pattern," "widespread," and the terms "actual harm that is not immediate jeopardy, and "no actual harm with a potential for minimal harm."

45. Neither the statutory provisions, the 1995 Regulations, nor the SOM provide IDPH surveyors with sufficient guidance about the method by which compliance is to be determined and remedies for noncompliance imposed.

46. Neither the statutory provisions, the 1995 Regulations nor the SOM provide Plaintiff's members with any meaningful guidance for determining whether their conduct is in "substantial compliance," or for distinguishing between deficiencies which result in a finding of "substandard quality of care," and those which trigger lesser findings and enforcement penalties. Indeed, neither HCFA nor the Secretary ever distribute the SOM to Plaintiff's members, thus giving them no notice of the requirements contained therein.

47. Additionally, the 1995 Regulations and survey procedures have been inconsistently and arbitrarily applied because of: (1) HCFA's failure to properly promulgate the SOM according to the APA; (2) HCFA's failure to improve accuracy and consistency in the application of the regulations; and (3) HCFA's frequent issuance of memoranda and letters which change policy and the definition of key terms.

48. For example, surveyors will cite a small number of findings as indicating a deficiency with a "widespread

scope," even in nursing facilities with a very large resident population. This is a result of the lack of provision of adequate guidance to surveyors in conducting a representative "sample" of the facility's residents and the lack of guidance regarding percentages of the sample needed to demonstrate a "pattern" or "widespread" scope.

49. Additionally, the "severity" factor has been inconsistently applied due to surveyors' subjective biases and their differing interpretations of what constitutes "actual harm," "more than minimal harm" and "immediate jeopardy."

50. Nationally, 73% of nursing facilities surveyed under the 1995 Regulations and the SOM have failed to meet the ne[illegible]erfection standards enforced thereunder since Ju[illegible], 1995. This is a marked increase from the under 6% found out of compliance with the OBRA '87 Requirements of Participation before the 1995 Regulations and the SOM took effect. *See* Summary of National Facility Compliance, Exhibit C.

E. Facilities Are Not Permitted Sufficient Due Process To Address The Key Difficulties Created By The Regulations.

51. Plaintiff's members are precluded from disputing factual findings at the time they are made by surveyors, because they are never given the surveyors' written findings at the time of the exit interview. As a result, they are precluded at that time from presenting the surveyors with any evidence, facts, or medical records that might correct the surveyors' findings before they are formalized.

52. Depending on the sanction or remedy imposed, the 1995 Regulations afford nursing facilities either no hearing of any kind, a "paper" hearing, or a post-deprivation hearing under 42 C.F.R. 498.

53. A finding of "substandard quality of care," pursuant to § 488.325(g) of the 1995 Regulations, requires the facility to provide IDPH with the name of the attending physician for each resident with respect to whom a finding of "substandard quality of care" has been made. IDPH is then required to notify the attending physicians of this finding, as well as the state board responsible for licensing the facility's administrator, which notification is stigmatizing to Plaintiff's members.

54. In addition, the "substandard quality of care" finding precludes a nursing facility from conducting federally approved NATCEP training programs for its nurse aides. Since nurse aides provide direct care to residents and turnover is high for such staff, the inability of a facility to provide ongoing on-site NATCEP training of new staff jeopardizes the facility's ability to train its nurse aids appropriately and to continue operations for any significant period of time.

55. Notwithstanding the hardships created by these sanctions, they are imposed without giving the facilities an opportunity for a hearing of any kind.

56. If a facility is found not to be in "substantial compliance" 90 days subsequent to a finding of "substandard quality of care," the 1995 Regulations and the SOM require that HCFA and IDPH must also impose a ban on payments for new admissions; placement of a

state monitor, or termination of the provider agreement. These remedies are imposed prior to any hearing.

57. The 1995 Regulations circumvent the facility's ability at a hearing to contest the conclusions of a survey. Instead, the facility may contest only the facts surrounding specific findings of non-compliance and the size of any civil money penalties imposed. 42 C.F.R. § 488.408(g). For example, a facility would be permitted to contest whether a resident's hair was properly combed (42 C.F.R. 483.15(a)), but would have no right to question a surveyor's equally factual conclusion that this indicates a "widespread" deficiency that poses "immediate jeopardy" to residents. 42 U.S.C. 1395i-3(h)(4) (Medicare); 42 U.S.C. 1396r(h)(5) (Medicaid); 42 C.F.R. § 488.410(a).

58. The SOM also restricts the facility's due process rights by mandating that a facility may not appeal: (1) the inconsistency of the survey team in citing deficiencies among facilities; (2) failure of the survey team to comply with a requirement of the survey process, thus destroying any assurances that the survey will be conducted in accordance with the statute. SOM, § 7212.

59. A facility may appeal only if sanctions actually are imposed. If a facility returns to substantial compliance before sanctions are imposed, no appeal is permitted, even if the facility was sanctioned with: (1) the loss of on-site Nurse Aid training (NATCEP); (2) full disclosure of stigmatizing and potentially erroneous survey findings to the public, to the State long term care ombudsman, the Illinois Department of Professional Regulation, and referring physicians; (3) the

requirement that the facility carry all prior deficiencies on its record for the next five years, where they can impact future survey procedures and aggravate sanctions that are imposed using historical trends; (4) the requirement that the facility carry the "substandard quality of care" label into its next survey, which label entails, *inter alia*, the loss of any ability to appeal the citation of even a potentially erroneous "repeat" finding during the survey.

60. In addition to the aforementioned limited post-deprivation hearing, the regulations provide for, under limited circumstances, an informal dispute resolution, or "paper hearing." In this process, the facility may contest through the mail the survey results of a standard or complaint survey, by submitting documentation to the state survey agency (IDPH) for review. As a matter of practice, any "paper hearing" requested by a facility is "adjudicated" by the same IDPH employee who reviewed the survey findings and issued the statement of deficiencies for that nursing facility in the first place. Moreover, this "adjudication" is conducted under the presumption that all the facts presented in the "paper hearing" were already presented to the surveyors during the survey, or at the exit interview. This presumption is often false due to the failure of the surveyors, under current procedures, to inform facilities of their proposed factual findings during the survey or exit interview.

61. The only sanction stayed by a facility's request for any "paper" or other hearing is the collection (but not the imposition) of civil money penalties, or CMPs. The 1995 Regulations specify, moreover, that, in considering appeals of the CMP range selected, the

presiding official must apply a "clearly erroneous" standard of review and, should any basis for the imposition of CMPs exist, may not: (1) reduce the CMP to zero; (2) review the government's exercise of discretion to impose a CMP; or (3) consider any factors other than those which HCFA and IDPH may consider. 42 U.S.C. 488.438(e). These limitations are further evidence of HCFA's attempt to legislate away the facility's due process rights through the 1995 Regulations.

62. The 1995 Regulations prescribe a limited system to contest these remedies in a full post-deprivation hearing. For Medicaid facilities, the State is required to complete this hearing within 120 days after the deprivation. 42 C.F.R. § 431.153(b).

63. On information and belief, a full post-deprivation hearing regarding Medicare termination presently does not occur until at least 6 months subsequent to the imposition of the sanction.

F. Defendants' Inconsistent And Arbitrary Enforcement Practices Under The 1995 Regulations Have Caused The Number Of Facilities Found Out Of Compliance With The Requirements Of Participation To Soar.

64. Plaintiff does not complain of the OBRA '87 Requirements of Participation themselves, but only the survey, certification and enforcement scheme implemented in the 1995 Regulations, and SOM and other "informal" interpretations of the SOM. Indeed, under 6% of facilities surveyed nationally under the enforcement scheme existing prior to promulgation of the 1995 Regulations were found to be out of substantial compliance with the 1990 Requirements of Participation. *See* Exhibit D "Trends in Percent of Facilities With Level A Violations" (American Health Care Association Deficiency Report, September 1995).

65. Beginning July 1, 1995, nursing facilities nationwide began being surveyed pursuant to the 1995 Regulations and the SOM. As a result of this new enforcement scheme, 6,050 out of 8,711, or 73%, of the facilities surveyed nationally were found to be out of compliance, and 2,623 (30%) of those facilities were scheduled for termination. *See* Exhibit C.

66. Furthermore, the implementation of the 1995 Regulations and the SOM have resulted in varying results from state to state. In Illinois, 73% of facilities were found to be out of compliance. Meanwhile, in Michigan, 99% of the facilities surveyed were found to be out of compliance, Indiana's nursing facilities were 86% out of compliance, Minnesota facilities were 90% out of compliance, Ohio facilities were 87% out of compliance, and Wisconsin facilities were 80% out of compliance. *See* Exhibit C.

67. Of the Illinois nursing facilities surveyed to date under the new regulations and SOM, at least 22 have received notices from HHS that their providers agreements will be terminated.

68. The enforcement of the 1995 Regulations and the SOM will have a substantial impact in Illinois because, of the 90,000 nursing home beds in use in Illinois, only about 31% are financed by private pay or private insurance. The remaining 68% are subject to 1995 regulations and the SOM because they serve Medicaid

and/or Medicare patients almost exclusively, and would not exist but for Medicaid and Medicare reimbursement, having been constructed, acquired or expanded to provide care for such patients. *See* IDPH Long Term Care Facility Statewide Summary Profile, Exhibit E). Many of these facilities could not have received bank financing or a certificate of need if they had not been certified and entered into provider agreements with HHS and IDPA, and many of them would be rendered immediately in default on their mortgage agreements should termination of their provider agreements occur.

MEDICAID-ONLY MEMBERS' CLAIMS

COUNT I
Enforcement Regulations Are Void For Vagueness

69. Plaintiff, on behalf of its Medicaid-Only members incorporates paragraphs 1-13, 17-23, 27-68 above as though set forth specifically herein.

70. The 1995 Regulations promulgated by the Defendant Secretary of HHS which establish procedures under the Medicaid program for the survey and certification of long-term care facilities, as well as the penalties for noncompliance, as monitored and enforced by HCFA, are unconstitutionally vague in that they fail to provide an individual of ordinary intelligence a reasonable opportunity to comply with their requirements.

71. The 1995 Regulations are unconstitutionally vague as to the definition of those key factors which are used by surveyors to determine "substantial compliance" and "substandard quality of care." Specifically,

the terms "actual harm," "minimal harm," "isolated," "pattern" and "widespread" are left undefined. This forces surveyors to make *ad hoc*, subjective determinations concerning the factors which must be weighed in reaching the conclusion that a facility is not in "substantial compliance" or provides "substandard quality of care."

72. This lack of specificity has resulted in arbitrary and discriminatory enforcement of the regulations. Certain Illinois nursing facilities have been found to be in noncompliance with the certification standards, as well as providing "substandard quality of care" while others with the same types of deficiencies have been found to be in "substantial compliance." This pattern of arbitrary and discriminatory enforcement is clear when compared to the dramatically differing rates of noncompliance and "substandard quality of care" found in facilities in other states.

73. The Secretary's failure to promulgate clear regulations for the determination of deficiencies deprives the Plaintiff's Medicaid-Only members of both fair notice of the deficiencies for which they will be penalized, as well as fair enforcement of the regulations, in violation of their rights to due process under the Fifth and Fourteenth Amendments to the United States Constitution.

COUNT II
Violations Of The Administrative Procedures Act (APA)

74. Plaintiff, on behalf of its Medicaid-Only members incorporates paragraphs 1-10, 17-23, 27-73 above as though set forth specifically herein.

75. The 1995 Regulations and the SOM pertaining to the Medicaid program violate the Administrative Procedure Act because they promulgate substantive rules that deviate from and exceed the legislative mandate of OBRA '87 in violation of the APA. Consequently, those survey methods, procedures and forms that exceed the mandate of OBRA '87 are illegal, void and of no effect.

76. The survey methods, procedures and forms contained in the SOM, HCFA Program letters, and other informal publications applicable to the Medicaid program that Defendants have required surveyors to use are also substantive rules that should be declared illegal, void and of no effect in that:

A. they were not promulgated in accordance with the notice and comment requirements of the APA, and are otherwise contrary to law because Defendants failed to provide an adequate statement of basis and purpose of the rule, in violation of the APA. 5 U.S.C. §§ 553 *et seq.*, 706.

B. the survey methods, procedures and forms contained in these publications deviate from and exceed the mandate of OBRA '87 and the 1995 Regulations, in violation of the APA.

COUNT III
Procedural Due Process

77. Plaintiff, on behalf of its Medicaid-Only members incorporates paragraphs 1-13, 17-23, 27-76 above as though set forth specifically herein.

78. Plaintiff's Medicaid-Only members have a protectable property interest in their participation in the Medicaid Program because:

A. The nursing facilities entered into the provider agreements in reliance on and with the expectation that HHS and IDPA would engage in the good faith performance of those agreements, such that their participation in the Medicaid program would continue from year to year, subject to reasonable regulation and enforcement of health and safety standards.

B. Over 95% of the Medicaid-Only members' beds currently in use are devoted principally to Medicaid residents, such that it would be impossible for the Plaintiff's Medicaid-Only members to convert their facilities into "private pay" facilities;

C. Most of the Plaintiff's Medicaid-Only members' beds make up 98% of their census and would not have been able to receive bank financing or a Certificate of Need absent the promise of significant Medicaid funding;

D. The Plaintiff's Medicaid-Only members are prohibited from voluntarily withdrawing from the Medi-

caid program by transferring Medicaid patients out. 42 C.F.R. § 482.12(a)(2).

79. Plaintiff's Medicaid-Only members also have a liberty interest in their reputation for quality care, which reputation is damaged by publication and dissemination to health professionals, family members and the general public of survey results and termination notices, which actions are taken without a hearing of any kind.

80. A determination that a nursing facility is not in "substantial compliance" or provides "substandard quality of care" carries with it penalties sufficiently severe that their imposition can jeopardize a facility's ability to continue operations. Yet pursuant to 42 U.S.C. § 488.408(g), a facility may not appeal the choice of remedy or the factors considered in selecting remedies.

81. In addition, the regulations provide no provision whereby a facility may challenge its designation as providing "substandard quality of care" if such facilities correct all alleged deficiencies before sanctions are imposed (as the regulations require them to do). Facilities that have thus corrected the deficiencies that resulted in the "substandard quality of care" designation by the date certain nonetheless will be considered to have provided "substandard quality of care" for the purposes of the next survey cycle. This non-appealable designation thus exposes the provider to enhanced and accelerated enforcement penalties in subsequent survey cycles.

82. After the facilities' initial survey, the regulations specify that a nursing facility may not utilize "informal dispute resolution." Therefore, nursing facilities do not have any "paper due process" to contest any deficiency that is cited in revisit surveys.

83. Due process requires that a party whose conduct is made subject to administrative action be given an opportunity to contest the validity of such action. Defendants have violated the rights of the Medicaid-Only members to due process of law under the Fifth and Fourteenth Amendments of the United States Constitution: (1) by failing to permit a challenge to a surveyor's assignment of "scope" and "severity" levels; (2) by failing to permit a challenge of the factors applied by HCFA or IDPH in determining enforcement remedies; (3) by providing no mechanism whereby "date certain" facilities can challenge a "substandard quality of care" determination; (4) by restricting the rights of facilities to contest even erroneous "repeat findings;" and (5) by limiting the ability to appeal the range of CMPs.

MEDICARE MEMBERS' CLAIMS

Count IV
Enforcement Regulations Are Void For Vagueness

84. Plaintiff, on behalf of its Medicare members incorporates paragraphs 1-10, 14-17, 24-68 above as though set forth specifically herein.

85. The 1995 Regulations promulgated by the Defendant Secretary of HHS which establish procedures under the Medicare program for the survey

and certification of long-term care facilities, as well as the penalties for noncompliance, as monitored and enforced by HCFA, are unconstitutionally vague in that they fail to provide an individual of ordinary intelligence a reasonable opportunity to comply with their requirements.

86. The 1995 Regulations are unconstitutionally vague as to the definition of those key factors which are used by surveyors to determine "substantial compliance" and "substandard quality of care." Specifically, the terms "actual harm," "minimal harm," "isolated," "pattern" and "widespread" are left undefined. This forces surveyors to make *ad hoc*, subjective determinations concerning the factors which must be weighed in reaching the conclusion that a facility is not in "substantial compliance" or provides "substandard quality of care."

87. This lack of specificity has resulted in arbitrary and discriminatory enforcement of the regulations. Certain Illinois nursing facilities have been found to be in noncompliance with the certification standards, as well as providing "substandard quality of care" while others with the same types of deficiencies have been found to be in "substantial compliance." This pattern of arbitrary and discriminatory enforcement is clear when compared to the dramatically differing rates of noncompliance and "substandard quality of care" found in facilities in other states.

88. The Secretary's failure to promulgate clear regulations for the determinations of deficiencies deprives the Plaintiff's Medicare members of both fair notice of the deficiencies for which they will be

penalized, as well as fair enforcement of the regulations, in violation of their rights to due process under the Fifth and Fourteenth Amendments to the United States Constitution.

COUNT V
Violation of Social Security Act

89. Plaintiff, on behalf of its Medicare members incorporates paragraphs 1-10, 14-17, 27-68, 84-88 above as though set forth specifically herein.

90. The applicable Medicare statute provides that HHS and IDPH "shall implement programs to measure and reduce inconsistency in the application of survey results among surveyors." 42 U.S.C. § 1395i-3(g)(2)(D). This requirement is carried over into the regulations at 42 C.F.R. § 488.312, which states: "HCFA does and the survey agency must implement programs to measure accuracy and improve consistency in the application of survey results and enforcement remedies."

91. To date neither HHS, HCFA, nor IDPH have taken adequate measures to ensure survey consistency. As a direct result, nursing facilities in Illinois are not being surveyed consistently, and have been inappropriately identified as both out of compliance and providing substandard quality of care, in violation of the Social Security Act.

COUNT VI
Violations Of The Administrative Procedures Act (APA)

92. Plaintiff, on behalf of its Medicare members incorporates paragraphs 1-10, 14-17, 24-68, 84-91 above as though set forth specifically herein.

93. The 1995 Regulations and the SOM pertaining to the Medicare program violate the Administrative Procedure Act because they promulgate substantive rules that deviate from and exceed the legislative mandate of OBRA '87 in violation of the APA. Consequently, those survey methods, procedures and forms that exceed the mandate of OBRA '87 are illegal, void and of no effect.

94. The survey methods, procedures and forms contained in the SOM, HCFA Program letters, and other informal publications applicable to the Medicare program that Defendants have required surveyors to use are also substantive rules that because should be declared illegal, void and of no effect in that:

A. they were not promulgated in accordance with the notice and comment requirements of the APA, and are otherwise contrary to law because Defendants failed to provide an adequate statement of basis and purpose of the rule, in violation of the APA. 5 U.S.C. §§ 553 *et seq.*, 706,

B. the survey methods, procedures and forms contained in these publications deviate from and exceed the mandate of OBRA '87 and the 1995 Regulations, in violation of the APA.

COUNT VII
Procedural Due Process

95. Plaintiff, on behalf of its Medicare members incorporates paragraphs 1-10, 14-17, 24-68, 84-94 above as though set forth specifically herein.

96. Plaintiff's Medicare members have a protectable property interest in their participation in the Medicare program because:

A. The nursing facilities entered into the provider agreements in reliance on and with the expectation that HHS would engage in the good faith performance of those agreements, such that their participation in the Medicare program would continue from year to year, subject to reasonable regulation and enforcement of health and safety standards.

B. The Plaintiff's Medicare members are prohibited from voluntarily withdrawing from the Medicare program by transferring Medicare patients out. 42 C.F.R. § 483.12(a)(2).

97. Plaintiff's Medicare members also have a liberty interest in their reputation for quality care, which reputation is damaged by publication and dissemination to health professionals, family members and the general public of survey results and termination notices, which actions are taken without a hearing of any kind.

98. A determination that a nursing facility is not in "substantial compliance" or provides "substandard quality of care" carries with it penalties sufficiently severe that their imposition can jeopardize a facility's

ability to continue operations. Yet pursuant to 42 U.S.C. § 488.408(g), a facility may not appeal the choice of remedy or the factors considered in selecting remedies.

99. In addition, the regulations provide no provision whereby a facility may challenge its designation as providing "substandard quality of care" if such facilities correct all alleged deficiencies before sanctions are imposed (as the regulations require them to do). Facilities that have thus corrected the deficiencies that resulted in the "substandard quality of care" designation by the date certain nonetheless will be considered to have provided "substandard quality of care" for the purposes of the next survey cycle. This non-appealable designation thus exposes the provider to enhanced and accelerated enforcement penalties in subsequent survey cycles.

100. After the facilities' initial survey, the regulations specify that a nursing facility may not utilize "informal dispute resolution." Therefore, nursing facilities do not have any "paper due process" to contest any deficiency that is cited in revisit surveys.

101. Due process requires that a party whose conduct is made subject to administrative action be given an opportunity to contest the validity of such action. Defendants have violated the rights of the Medicare members to due process of law under the Fifth and Fourteenth Amendments of the United States Constitution: (1) by failing to permit a challenge to a surveyor's assignment of "scope" and "severity" levels; (2) by failing to permit a challenge of the factors applied by HCFA and IDPH in determining enforcement remedies; (3) by providing no mechanism whereby "date certain" facilities can challenge a "substandard quality of care" determination; (4) by restricting the rights of facilities to contest even erroneous "repeat findings;" and (5) by limiting the ability to appeal the range of CMPs.

RELIEF REQUESTED ON BEHALF OF PLAINTIFF'S MEDICAID-ONLY MEMBERS

WHEREFORE, for all the above and foregoing Counts, Plaintiff respectfully requests that this Honorable Court grant it the following relief for its Medicaid-Only members:

A. Issue a judgment declaring that those factors set forth in 42 C.F.R. § 488.404 concerning the Survey and Certification of Long-Term Care Facilities pertaining to the Medicaid program are unconstitutionally vague and violate Plaintiff's Medicaid-Only members' rights to due process under the Fifth and Fourteenth Amendments to the United States Constitution;

B. Issue a judgment declaring that, by failing to promulgate survey methods, procedures and forms pursuant to public notice and comment requirements, Defendants have imposed substantive obligations on nursing facilities in violation of the Administrative Procedures Act;

C. Issue a judgment declaring that the appeal procedures provided under the regulations are inadequate, unjust, and violate Plaintiff's Medicaid-Only members' rights to procedural due process;

D. After a hearing, issue a preliminary injunction restraining the Defendants from requiring the disclosure to attending physicians and state licensing officials of survey results for any of Plaintiff's Medicaid-Only members found to have provided "substandard quality of care," until such time as Plaintiff's claims can be addressed at trial;

E. After a hearing, issue a preliminary injunction restraining Defendants from imposing or collecting civil monetary penalties from Plaintiff's members as a remedy for any deficiency until such time that Plaintiff's Medicaid-Only claims can be addressed at trial;

F. After a hearing, issue a preliminary injunction restraining Defendants from imposing upon Plaintiff's Medicaid-Only members any ban on payment as a remedy for any deficiency until such time that Plaintiff's claims can be addressed at trial;

G. After a hearing, issue a preliminary injunction restraining Defendants from interfering with any NATCEP nurse aide training and competency evaluation program conducted by Plaintiff's Medicaid-Only members following a member's citation for any deficiency which results in a finding of "substandard quality of care," until such time that Plaintiff's claims can be addressed at trial;

(a) After a trial, permanently enjoin Defendants from the actions set forth in paragraphs D through G hereto;

(b) Award Plaintiff its reasonable attorney's fees and expenses to the extent allowable under law; and

(c) Enter such other and further relief as this Honorable Court deems just and proper.

RELIEF REQUESTED ON BEHALF OF PLAINTIFF'S MEDICARE MEMBERS

WHEREFORE, for all the above and foregoing Counts, Plaintiff respectfully requests that this Honorable Court grant it the following relief for its Medicare members:

A. Issue a judgment declaring that those factors set forth at 42 C.F.R. § 488.404 concerning the Survey and Certification of Long-Term Care Facilities pertaining to the Medicare program are unconstitutionally vague and violate Plaintiff's Medicare members' rights to due process under the Fifth and Fourteenth Amendments to the United States Constitution;

B. Issue a judgment declaring that Defendants have failed to meet their obligations under federal law to ensure consistency in survey, certification and application of enforcement remedies.

C. Issue a judgment declaring that, by failing to promulgate survey methods, procedures and forms pursuant to public notice and comment requirements, Defendants have imposed substantive obligations on nursing facilities in violation of the Administrative Procedures Act;

D. Issue a judgment declaring that the appeal procedures provided under the regulations are inadequate, unjust, and violate Plaintiff's Medicare members rights to procedural due process;

E. After a hearing, issue a preliminary injunction restraining the Defendants from requiring the disclosure to attending physicians and state licensing officials of survey results for any of Plaintiff's Medicare members found to have provided "substandard quality of care," until such time as Plaintiff's claims can be addressed at trial;

F. After a hearing, issue a preliminary injunction restraining Defendants from imposing or collecting civil monetary penalties from Plaintiff's members as a remedy for any deficiency until such time that Plaintiff's Medicare claims can be addressed at trial;

G. After a hearing, issue a preliminary injunction restraining Defendants from imposing upon Plaintiff's Medicare members any ban on payment as a remedy for any deficiency until such time that Plaintiff's claims can be addressed at trial;

H. After a hearing, issue a preliminary injunction restraining Defendants from interfering with any NATCEP nurse aide training and competency evaluation program conducted by Plaintiff's Medicare members following a member's citation for any deficiency which results in a finding of "substandard quality of care," until such time that Plaintiff's claims can be addressed at trial;

(a) After a trial, permanently enjoin Defendants from the actions set forth in paragraphs E through H hereto;

(b) Award Plaintiff its reasonable attorney's fees and expenses to the extent allowable under law; and

(c) Enter such other and further relief as this Honorable Court deems just and proper.

Respectfully Submitted,

ILLINOIS COUNCIL ON LONG-TERM CARE

By /s/ NEIL E. HOLMEN
One of Its Attorneys

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[Exhibit A To Amended Complaint]

[Excerpts]

State Operations Manual
HCFA Publication 7
Revision 273
June 1995

NEW MATERIAL	REVISED PAGES	REPLACE PAGES
Part 7, Table of Contents	7-1 - 7-3 (3 pp.)	—
Secs. 7000 – 7907	7-5 - 7-80 (75 pp.)	—
List of Exhibits	5-6.1 – 5.6.3 (3 pp.)	5-6.1 - 5-6-2 (2 p.)
Exhibits 139 -148	5-707 – 5.723 (16 pp.)	—

CHANGED PROCEDURES EFFECTIVE DATE: JULY 1, 1995

These procedures are effective for surveys which begin on or after July 1, 1995, to be consistent with the Survey, Certification and Enforcement Regulation for SNFs and NFs which was published in the Federal Register on November 10, 1994 and is effective on July 1, 1995.

Section 7000. Introduction. Section 7000 provides background and philosophy for the survey and enforcement procedures outlined in this part.

Section 7001. Definitions and Acronyms. Section 7001 provides definitions and acronyms used in this part.

Section 7002. Change in Certification Status for Medicaid NFs. Section 7002 instructs procedures to follow when a Medicaid NFs wishes to participate as a Medicare SNF.

Section 7004. SNFs - Citations and Description. Section 7004 describes what a SNF is and its statutory basis.

Section 7006. NFs - Citations and Description. Section 7006 describes what a NF is and its statutory basis.

Section 7008. Types of Facilities That May Qualify as SNFs and NFs. Section 7008 describes the types of facilities that may qualify as a SNF or NF.

Section 7010. SNFs Providing Outpatient Physical Therapy, Speech Pathology, or Occupational Services. Section 7010 describes the services that a SNF may provide.

Section 7014. Special Waivers Applicable to SNFs and NFs. Section 7014 describes the requirements for nursing staff waivers, life safety code waivers, and variations of patient room size and/or beds per room.

Section 7200. Emphasis, Components and Applicability. Section 7200 describes the tasks to be completed for surveying SNFs and NFs.

Section 7201. Survey Team Size and Composition – Length of Survey. Section 7201 describes the size of survey teams, qualification of surveyors, what types of surveyors should be represented on a survey team and the general length of a survey.

* * * * *

Chapter VII

SURVEY AND ENFORCEMENT PROCESS FOR SNFs AND NFs

Survey Process

Certification of Compliance and Noncompliance Process

Enforcement Process

Remedies

Continuation of Payment During Correction

Complaints

Program Management

Disclosure

* * * * *

[7-39] **Enforcement Process**

7400. ENFORCEMENT REMEDIES FOR SNFs AND NFs

A. Introduction. Sections 1819(h) and 1919(h) of the Act, as well as 42 CFR 488.404, 488.406, and 488.408, provide that HCFA or the State may impose one or more remedies in addition to, or instead of, termination of the provider agreement when the State or HCFA finds that a facility has deficiencies. The remedies available to the RO, or the SMA, or both, as appropriate, are listed in subsection C.

B. General. OBRA 1987 mandated the elimination of the preexisting hierarchical participation requirements and their replacement with a system capable of detecting and responding to deficiencies with any participation requirement. Therefore, the new nursing home enforcement protocol/procedures are based on the premise that all requirements must be met and enforced. These requirements take on greater or lesser significance depending on the specific circumstances and resident outcomes in each facility.

A SNF, NF, or dually-participating facility (SNF/NF) will be subject to one or more enforcement remedies for noncompliance with one or more participation requirements. Each facility that has deficiencies (other than those isolated deficiencies that have been determined to constitute no actual harm with potential for only minimal harm) must submit an acceptable PoC. HCFA's requirement relative to submittal of

PoCs can be found in §2728.B. A PoC is not an enforcement remedy.

C. Listing of Remedies.

1. Available Enforcement Remedies. In accordance with 42 CFR 488.406, the following remedies are available:

- Termination of the provider agreement;
- Temporary management;
- Denial of payment for all Medicare and/or Medicaid residents by HCFA;
- Denial of payment for all new Medicare and/or Medicaid admissions;
- CMPs;
- State monitoring;
- Transfer of residents;
- Transfer of residents with closure of facility;
- DPoC;
- Directed in-service training; and
- Alternative or additional State remedies approved by HCFA. [7-40]

2. Mandatory Enforcement Remedies. Regardless of what other remedies the SMA may want to establish in addition to the remedy of termination of the provider agreement, it must establish, at a minimum, these statutorily specified remedies or an approved alternative to these specified remedies:

- Temporary management;
- Denial of payment for all new admissions;
- CMPs;
- Transfer of residents;
- Transfer of residents with closure of facility; and
- State monitoring.

The SMA may establish additional or alternative remedies provided that the State has been authorized to do so under its State plan by HCFA. Guidance on the review and approval (or disapproval) of State Plan amendment requests for alternative or additional remedies can be found in §7805.

3. Availability of SMA Remedies To RO in Dually-Participating Facilities. Whenever a SMA's remedy is unique to its State plan and has been approved by HCFA, then that remedy may also be imposed by the RO against the Medicare provider agreement of a dually-participating facility in that State. Where HCFA has approved a State's ban on ad-

missions remedy as an alternative remedy under the State plan, HCFA may impose this remedy relative to only Medicare and Medicaid residents. Only the State can ban the admission of private pay residents.

D. Measuring Seriousness of Deficiencies. Measuring the seriousness of deficiencies is only for the purpose of determining the enforcement response most appropriate for specific degrees of noncompliance. The system by which the seriousness of deficiencies is rated (i.e., harm and scope factors), is a national system to be used by States and HCFA. Immediate jeopardy has historically been determined by guidance provided in Appendix Q of the Interpretive Guidelines and will continue to be determined using that guidance. Appendix P of the Interpretive Guidelines provides guidance on how to determine the seriousness of nonimmediate jeopardy deficiencies.

E. Selection of Remedies.

1. Factors That Must Be Considered When Selecting Remedies. In order to select the appropriate remedy(ies) for a facility's noncompliance, the seriousness of the deficiency(ies) must first be assessed, because specific levels of seriousness are correlated with specific categories of enforcement responses. The assessment factors that must be used to determine the seriousness of deficiencies are presented on the visual matrix which follows later in this subsection. These factors are also listed below. They relate to whether the deficiencies constitute:

- No actual harm with a potential for minimal harm;
- No actual harm with a potential for more than minimal harm but not immediate jeopardy;

[7-41]

- Actual harm that is not immediate jeopardy; or,
- Immediate jeopardy to resident health or safety.

AND, whether deficiencies:

- Are isolated;
- Constitute a pattern; or,
- Are widespread.

[7-42]

	Isolated	Pattern	Widespread
Immediate Jeopardy to Resident Health or Safety	J PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	K PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	L PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2
Actual Harm that is not Immediate Jeopardy	G PoC Required* Cat. 2 Optional: Cat. 1	H PoC Required* Cat. 2 Optional: Cat. 1	I PoC Required* Cat. 2 Optional: Cat. 1 Optional: Temporary Mgmt.
No Actual Harm with Potential for More than Minimal Harm that is not Immediate Jeopardy	D PoC Required* Cat. 1 Optional: Cat. 2	E PoC Required* Cat. 1 Optional: Cat. 2	F PoC Required* Cat. 2 Optional: Cat. 2
No Actual Harm with Potential for Minimal Harm	A No PoC No Remedies Commitment to Correct Not on HCFA-2567	B PoC	C PoC

Substandard quality of care: any deficiency in §4813 Resident Behavior and Facility Practices, §483.15 Quality of Life, or in §483.25, Quality of Care, that constitutes: immediate jeopardy to resident health or safety; or, a pattern of or widespread actual harm that is not immediate jeopardy; or, a widespread potential for more than minimal harm that is not immediate jeopardy, with no actual harm.

Substantial compliance

Remedy Categories

Category 1 (Cat.1)

Directed Plan of Correction
State Monitor; and/or
Directed In-Service Training

Category 2 (Cat. 2)
Denial of Payment for New Admissions
Denial of Payment for All Individuals;
imposed by HCFA: and/or Civil Money
Penalties: $50-$3,000/day

Category 3 (Cat. 3)

Temporary Management
Termination

Optional:

Civil Money Penalties
$3,050 - $10,000/day

Denial of payment for new admissions must be imposed when a facility is not in substantial compliance within 3 months after being found out of compliance.

Denial of Payment and State Monitoring must be imposed when a facility has been found to have provided substandard quality of care on three consecutive standard surveys.

Note: Termination may be imposed by the State or HCFA at any time when appropriate.

Following a determination of scope and severity, the SA enters on Form HCFA-2567L the letter corresponding to the box of the grid for at least any deficiency which constitutes substandard quality of care and any deficiency which drives the choice of a required remedy

category. The SA enters this letter in ID prefix tag column immediately below the tag number of the Form HCFA-2567L. Deficiencies falling in box A are recorded on Form A.

* This is required only when a decision is made to impose alternative remedies instead of or in addition to termination. [7-43]

Once the seriousness of the deficiency(ies) is determined, and the decision is made to impose remedies instead of, or in addition to, termination, the RO, or the SA, or both, as determined in accordance with §7300, must select one or more remedies from the remedy category (or a HCFA approved alternative or additional State remedy) associated with the specific level of noncompliance in accordance with the visual matrix above. The remedy category to be applied against facility noncompliance will be determined by the most serious deficiency(ies) identified, i.e., deficiencies falling into the box closest to the highest harm and scope rated box. Additional factors may be considered, including but not limited to, those provided in subsection 2.

2. Other Factors That May Be Considered in Selecting Enforcement Remedy Within Remedy Category. Additional factors that may be considered to assist in determining which and/or how many remedy(ies) to impose within the available remedy categories for particular levels of noncompliance, include but are not limited to:

- The relationship of one deficiency to other deficiencies to determine;
- The facility's prior history of noncompliance in general and specifically with reference to the cited deficiency(ies); and
- The likelihood that the selected remedy(ies) will achieve correction and continued compliance.

EXAMPLE: If failure to spend money is the root cause of the facility's noncompliance, then any CMP that is imposed should at least exceed the amount saved by the facility by not maintaining compliance.

3. Requirement For Facility To Submit PoC. Except when a facility has isolated deficiencies that constitute no actual harm with potential for no more than minimal harm, each facility that has a deficiency must submit a PoC for approval. For any PoC to be acceptable, it must address the four elements provided in §7304.B. Those facilities having isolated deficiencies that constitute no actual harm with potential for minimal harm need not submit a PoC. The RO approves PoCs for State-operated facilities and for validation surveys; the SA approves all others. The process and timetable for HCFA's approval of PoCs under the continuation of payment provision is in accordance with §7600. The requirement that providers submit a PoC can be found in §2728.B.

F. When To Select Remedy From Specific Remedy Category.

1. Category 1. Select at least one remedy from category 1 when there:

   - Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

   - Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

   EXCEPT when the facility is in substantial compliance, one or more of the remedies in category 1 may be applied to any deficiency.

[7-44] CATEGORY 1 remedies include:

- DPoC (see §7500);

- State monitoring (see §7504); and

- Directed in-service training (see §7502.)

NOTE: The SA as an agent of HCFA or the SMA may impose one or more category 1 remedies, as authorized by HCFA or the SMA, in accordance with §7314.

2. Category 2. Select at least one remedy from category 2 when there are:

- Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

- One or more deficiencies (regardless of scope) that constitute actual harm that is not immediate jeopardy.

  EXCEPT when the facility is in substantial compliance, one or more of the remedies in category 2 may be applied to any deficiency.

  NOTE: The SMA does not have the statutory authority to impose the remedy of denial of payment for all Medicare and/or Medicaid residents.

CATEGORY 2 remedies include:

- Denial of payment for all new Medicare and/or Medicaid admissions (see §7506);

- Denial of payment for all Medicare and/or Medicaid residents, imposed by the RO (see §7508); and

- CMPs of $50 - $3,000 per day of noncompliance. (See §7510.)

3. Selection From Category 3. Termination or temporary management, or both, must be selected when there are one or more deficiencies that constitute immediate jeopardy to resident health or safety. A CMP of $3,050 - $10,000 per day may be imposed in addition to the remedies of termination and/or temporary management. Temporary management is also an option when there are widespread deficiencies constituting actual harm that is not immediate jeopardy.

CATEGORY 3 remedies include:

- Temporary management (see §7550);
- Termination (see §7556); and
- CMPs of $3,050 - $10,000 per day of noncompliance optional, in addition to the remedies of termination and/or temporary management. (See §7510.)

> **NOTE:** Termination may be imposed by the SMA or the RO at any time when appropriate. Transfer of residents or transfer of residents with closure of facility will be imposed by the State as appropriate.

[Exhibit B to Amended Complaint]

[Seal omitted]

Health Care
Financing Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

DATE: DEC 06 1995

FROM: Deputy Bureau Director
Survey and Certification, HSQB

SUBJECT: Interim Revisit Policy

TO: Associate Regional Administrators
Division of Health Standards and Quality
Regions I - X

State Agency Directors

INTERIM POLICY: EFFECTIVE UPON RECEIPT

The purpose of this memorandum is to present an interim revision to the existing policy on when a State agency must conduct a revisit following a survey. We thank you for your many comments regarding criteria for revisits. We continue to analyze and plan to develop a final policy in this area after consultation with relevant parties.

It is recognized that resource limitations may not allow revisits in every instance that noncompliance is identified. Thus, it is necessary that we issue an interim policy at this time on when to conduct revisits. This policy will remain in effect until a final policy on

revisits is developed based on further analysis and consultation.

Revisits will no longer be required if the deficiency(-ies) are determined to fall into Boxes D, E, or F if there is no finding of substandard quality of care. However, a revisit may be conducted whenever you determine that a revisit is necessary, regardless of the level of deficiencies. The policy does not alleviate the responsibility for survey agencies to ensure that providers correct all deficiencies.

This interim policy revises the existing revisit policy, found at section 7317 of Transmittal No. 273, State Operations Manual. The provider would continue to be required to meet the four points for an acceptable Plan of Correction (PoC) specified in State Operations Manual, Transmittal No. 273, section 7304C. That is, the PoC must specify:

1. How corrective action will be accomplished for those residents who have been affected by the deficient practice;

2. How the facility will identify other residents having the potential to be affected by the same deficient practice;

3. What measures will be put into place or systemic changes made to ensure that the deficient practice will not recur; and

4. How the facility will monitor its corrective actions to ensure that the deficient practice is being corrected and will not recur, i.e., what program will be put into place to monitor the

continued effectiveness of the systemic changes?

If the State agency determines that the highest level of deficiency is D, E, or F and there is no finding of substandard quality of care, the State agency may, in lieu of a revisit, determine correction and compliance by accepting the facility's PoC, if it is:

1. reasonable;

2. addresses the problem; and

3. the facility submits evidence that it has monitored its corrective action as specified in the fourth requirement of the PoC.

If the survey agency subsequently as a result of a complaint or other means, determines that the facility had not corrected the problems identified by the earlier survey, the survey agency may consider that the facility is a poor performer and recommend immediate remedies.

This interim policy is intended to give relief to the States without removing facilities from their responsibility to maintain compliance. In a subsequent memorandum, we will specify a process for completing the HCFA-2567B congruent with this policy. In addition, we will be soliciting further consultations as we develop final policies in this area.

Once again, thank you for your assistance as we work together to successfully implement this process. If you have any questions, please call me, Debbie Schoenemann, or Vic Santoro at (410) 786-6763, (410) 786-6771, or (410) 786-6778, respectively.

/s/ ANTHONY J. TIRONE
ANTHONY J. TIRONE

[Exhibit C to Amended Complaint]

A) Survey Activity Summary for January 26, 1996

The report below represents cumulative totals of survey activity through the reporting date. The figures under the bold headings are exclusive of one another. For example, one State may have conducted 47 surveys since July 1 and may not have yet rendered a decision regarding compliance or enforcement on all 47 surveys. Another State may have conducted 39 surveys and rendered compliance and enforcement decisions on all.

SURVEY ACTIVITY SUMMARY	STARDARD SURVEYS	COMPLAINT SURVEYS
Surveys Completed	8711	12,640
Compliance Decisions Rendered	8353	11,345
Facilities in substantial compliance	2303 28%	8965 79%
Facilities with Level D and above deficiencies	6050 72%	2380 21%
Total immediate remedies proposed	235	106
Total with opportunity to correct	5815	2274
Facilities with substandard quality of care	1188 14%	352 3%
Dispute Resolution Reviewed	975	290
Total affirmed	451	192
Total revised	524	98
Facilities verified on revisit in substantial compliance	3039	770
Facilities verified on revisit NOT in substantial compliance	687	207

REMEDIES	REMEDIES PROPOSED		REMEDIES IMPOSED
	STANDARD	COMPLAINT	
State monitoring	677	304	106
Directed Plan of Correction	1155	318	125
Temporary Management	13	15	10
Denial of Payment for New Admissions	2145	607	192
Denial of Payment for All Residents	139	51	6
Directed Inservice Training	1746	617	67
Civil Money Penalty	2062	718	94
HCFA Approved Alternative State Remedy	31	5	5
Transfer of Residents/Closure of the Facility	0	0	1
Transfer of Residents	74	12	2
Termination	2623	1077	21

State Implementation Report 1

01/26/1996

1995 - 01/26/1996 STANDARD

Region 5	Surveys Complete	Comp In	%	Not	%	Tot	SQC	%	SQC Care	Life	Behavior	Int Rem Prop	Licensure Enforcement Ban	CMP	Closure	Other	Dispute Resolution Req	Rvwd	Aff	%	Rev	%
IL	613	223	36%	390	64%	613	61	10%	50	22	14	2	0	2	0	0	160	157	71	45%	86	55%
IN	262	36	14%	226	86%	262	47	18%	88	69	35	5	4	27	0	5	41	29	16	55%	13	45%
MI	208	7	3%	201	97%	208	70	34%	189	113	32	33	12	0	0	0	19	14	4	29%	10	71%
MN	131	13	10%	118	90%	131	16	12%	12	4	0	0	0	0	0	0	5	5	2	40%	3	60%
OH	457	64	14%	393	86%	457	97	21%	148	67	42	13	0	0	0	0	41	92	88	32	36%	56	64%
WI	216	48	23%	162	77%	210	11	5%	4	10	3	0	0	0	0	0	0	67	56	11	20%	45	80%
Totals	1,887	391	21%	1,490	79%	1,881	302	16%	491	285	126	53	16	29	0	46	384	349	136	39%	213	61%
Nat'l Totals	8,711	2,303	28%	6,050	72%	8,353	1,188	14%	1,803	1,099	441	235	86	158	0	112	1,180	975	451	46%	524	54%

State Implementation Report 1

01/26/1996

1995 - 01/26/1996

COMPLAINT

Region 5	Surveys Complete	Comp In	%	Comp Not	%	Tot	SQC	%	SQC Care	SQC Life	SQC Behavior	Im Rem Prop	Licensure Enforcement Ban	Licensure Enforcement CMP	Licensure Enforcement Closure	Licensure Enforcement Other	Dispute Resolution Req	Dispute Resolution Rvwd	Dispute Resolution Aff	%	Dispute Resolution Rev	%
IL	1,935	548	80%	387	20%	1,935	14	1%	9	3	3	2	0	0	0	0	133	133	84	63%	49	37%
IN	496	52	28%	135	72%	187	21	11%	19	14	11	2	0	13	0	0	22	22	18	82%	4	18%
MI	204	85	42%	119	58%	204	10	5%	10	0	4	8	1	0	0	0	9	9	5	56%	4	44%
MN	0	0	0%	0	0%	0	0	0%	0	0	0	0	0	0	0	0	0	0	0	0%	0	0%
OH	513	368	72 %	145	28%	513	28	5%	35	11	5	3	0	0	0	2	14	11	5	45%	6	55%
WI	357	333	93%	24	7%	357	1	0%	1	1	0	1	0	0	0	0	4	8	5	63%	3	38%
Totals	3,505	2,386	75%	810	25%	3,196	74	2%	74	29	23	16	1	13	0	2	182	183	117	64%	66	36%
Nat'l Totals	12,640	8,965	79%	2,380	21%	11,345	352	3%	516	212	126	106	14	46	1	21	346	290	192	66%	98	34%

State Implementation Report 2

01/26/1996

1995 - 01/26/1996 STANDARD

Region 5	Remedies											Scope And Severity											
	01	02	03	04	05	06	07	08	09	10	11	A	B	C	D	E	F	G	H	I	J	K	L
IL	1	54	0	50	14	336	231	0	0	64	16	264	383	508	568	651	189	120	51	18	4	1	14
IN	2	7	0	204	10	113	105	0	0	4	212	143	323	261	276	623	187	117	147	72	2	4	18
MI	201	0	0	30	0	0	117	0	0	0	201	104	266	184	649	665	369	335	144	115	6	3	11
MN	9	22	0	10	0	0	35	0	0	0	76	38	45	53	122	169	37	61	30	2	0	0	0
OH	137	0	0	302	0	0	2	0	0	0	421	344	292	269	878	896	450	191	142	66	1	1	3
WI	2	105	0	17	0	1	44	0	0	0	0	200	249	128	389	342	154	61	12	0	0	0	0
Totals	352	188	0	613	24	450	534	0	0	68	926	1,093	1,558	1,403	2,882	3,346	1,386	885	526	273	13	9	46
Nat'l Totals	677	1,155	13	2,145	139	1,746	2,062	31	0	74	2,623	4,748	5,470	5,136	8,083	9,650	4,362	3,768	2,083	927	36	63	77

State Implementation Report 2

01/26/1996

1995 - 01/26/1996

COMPLAINT

Region 5	Remedies											Scope And Severity											
	01	02	03	04	05	06	07	08	09	10	11	A	B	C	D	E	F	G	H	I	J	K	L
IL	0	28	0	31	1	263	157	0	0	0	0	71	90	64	183	98	40	112	34	1	2	2	2
IN	0	16	0	110	0	42	53	0	0	0	110	20	34	18	81	104	29	71	48	25	0	0	0
MI	107	1	0	3	0	0	45	0	0	0	113	18	5	6	59	25	8	56	5	0	4	0	0
MN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OH	68	0	0	69	0	0	0	0	0	0	125	46	37	28	96	79	30	50	22	17	1	1	2
WI	0	11	0	0	0	0	9	0	0	0	0	11	4	1	16	9	3	9	3	0	0	0	0
Totals	175	56	0	213	1	305	264	0	0	0	348	166	170	117	435	315	110	298	112	43	7	3	4
Nat'l Totals	304	318	15	607	51	617	718	5	0	12	1,077	567	634	522	1,311	1,268	633	1,135	517	206	33	54	39

State Implementation Report 3

01/26/1996

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STANDARD

Region 5	Revisits Conducted	Revisits In Compliance	%	Revisits Not in Compliance	%	Tot Comp	Cat 2 or 3 Remedies Recommended	%
IL	270	200	72%	78	28%	278	30	11%
IN	153	106	68%	51	32%	157	29	18%
MI	72	30	43%	39	57%	69	12	17%
MN	31	31	100%	0	0%	31	0	0%
OH	332	283	85%	49	15%	332	48	14%
WI	113	95	82%	21	18%	116	4	3%
Totals	971	745	76%	238	24%	983	123	13%
Nat'l Totals	3,712	3,039	82%	687	18%	3,726	448	12%

State Implementation Report 3

01/26/1996

1995 - 01/26/1996

COMPLAINT

Region 5	Revisits Conducted	Revisits In Compliance	%	Revisits Not in Compliance	%	Tot Comp	Cat 2 or 3 Remedies Recommended	%
IL	73	111	83%	22	17%	133	20	15%
IN	77	39	65%	21	35%	60	9	15%
MI	0	0	0%	0	0%	0	1	0%
MN	0	0	0%	0	0%	0	0	0%
OH	75	68	93%	5	7%	73	5	7%
WI	17	14	88%	2	13%	16	1	6%
Totals	242	232	82%	50	18%	282	36	13%
Nat'l Totals	948	770	79%	207	21%	977	146	15%

Sheet 1

				REMEDIES FORMALLY IMPOSED										
REMEDIES	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*TOTALS*		
REGION I														*KEY*
CT	0	0	0	0	0	0	2	0	0	0	0	2	1	*State Monitoring*
MA	3	1	2	4	0	1	1	0	0	0	1	13	2	*Directed PoC*
ME	0	1	2	2	0	1	2	0	0	0	0	8	3	*Temporary Manager*
NH	0	0	0	0	0	0	0	0	0	0	0	0	4	*Denial of Pmt - New*
RI	0	0	0	0	0	0	0	0	0	0	0	0	5	*Denial of Pmt - All*
VT	0	0	0	0	0	0	0	0	0	0	0	0	6	*Directed Inservice*
REGION II													7	*CMP*
NJ	0	2	0	1	0	2	4	0	0	0	0	9	8	*Alt State Remedy*
NY	0	0	0	3	0	0	0	0	0	0	0	3	9	*Transfer/Closure*
VI	0	1	0	0	0	0	0	0	0	0	0	1	10	*Transfer*
REGION III													11	*Termination*
DC	0	0	0	0	0	0	1	0	0	0	0	1		
DE	0	0	0	0	0	0	0	0	0	0	0	0		
MD	0	0	0	0	0	0	1	0	0	0	0	1		
PA	0	0	0	0	0	0	1	0	0	0	0	1		
VA	0	0	0	0	0	0	0	0	0	0	0	0		
WV	0	0	0	0	0	0	0	0	0	0	0	0		
REGION IV														
AL	0	0	0	0	0	1	1	0	0	0	1	3		
FL	0	0	0	0	0	0	10	0	0	0	11	21		
GA	1	96	0	0	0	7	0	0	0	0	0	104		
KY	1	0	0	0	1	0	2	0	0	0	0	4		
MS	0	0	0	0	5	0	8	5	1	0	0	19		
NC	0	0	0	0	0	1	3	0	0	0	0	4		
SC	1	1	0	5	0	0	1	0	0	0	3	11		
TN	1	0	0	0	0	0	3	0	0	0	2	6		
REGION V														
IL	0	1	0	19	0	30	0	0	0	0	1	51		
IN	1	0	0	10	0	1	2	0	0	0	0	14		
MI	1	0	0	0	0	0	0	0	0	0	0	1		
MN	0	0	0	0	0	0	0	0	0	0	0	0		
OH	34	0	0	34	0	0	4	0	0	0	0	72		
WI	0	0	0	0	0	0	0	0	0	0	0	0		

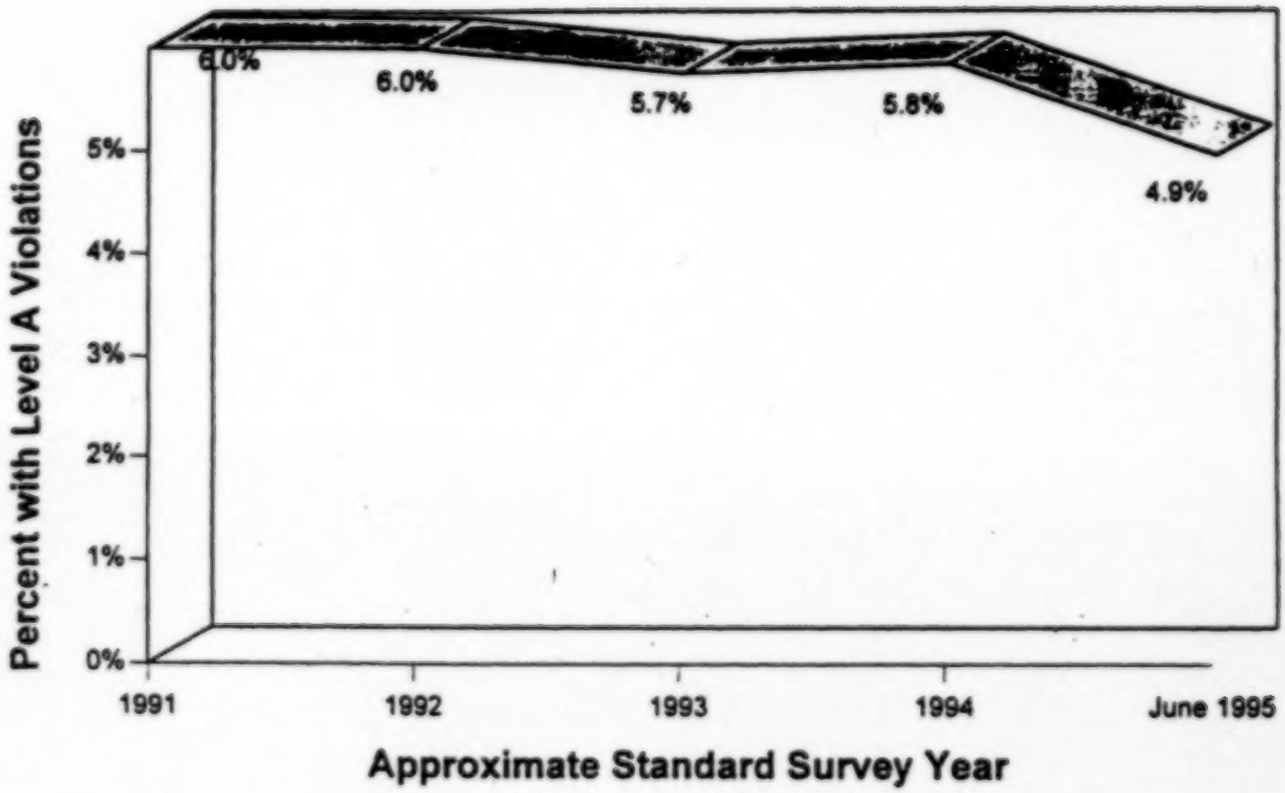
Sheet 1

				REMEDIES FORMALLY IMPOSED										
REMEDIES	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*TOTALS*		
REGION VI														*KEY*
AR	0	0	0	5	0	0	0	0	0	0	0	5	1	*State Monitoring*
LA	0	0	0	2	0	0	0	0	0	0	0	2	2	*Directed PoC*
NM	1	1	0	0	0	0	0	0	0	0	0	2	3	*Temporary Manager*
OK	0	0	0	2	0	1	0	0	0	0	0	3	4	*Denial of Pmt - New*
TX	5	5	0	37	0	17	29	0	0	0	1	94	5	*Denial of Pmt - All*
REGION VII													6	*Directed Inservice*
IA	3	0	0	2	0	0	1	0	0	0	0	6	7	*CMP*
KS	23	0	0	18	0	0	13	0	0	0	0	54	8	*Alt State Remedy*
MO	1	1	0	0	0	0	2	0	0	0	1	5	9	*Transfer/Closure*
NE	1	0	0	0	0	0	0	0	0	0	0	1	10	*Transfer*
REGION VIII													11	*Termination*
CO	0	0	0	0	0	0	0	0	0	0	0	0		
MT	0	0	0	0	0	0	0	0	0	0	0	0		
ND	0	0	0	0	0	0	0	0	0	0	0	0		
SD	0	0	0	0	0	0	0	0	0	0	0	0		
UT	0	0	0	0	0	0	0	0	0	0	0	0		
WY	0	1	0	1	0	1	0	0	0	0	0	3		
REGION IX														
AZ	0	0	0	0	0	0	0	0	0	0	0	0		
CA	29	5	4	19	0	3	0	0	0	2	0	62		
HI	0	0	0	0	0	0	0	0	0	0	0	0		
NV	0	6	2	3	0	0	0	0	0	0	0	11		
REGION X														
AK	0	0	0	1	0	0	0	0	0	0	0	1		
ID	0	0	0	0	0	0	1	0	0	0	0	1		
OR	0	0	0	13	0	1	2	0	0	0	0	16		
WA	0	3	0	11	0	0	0	0	0	0	0	14		
TOTALS	106	125	10	192	6	67	94	5	1	2	21	629		

[Exhibit D to Amended Complaint]

Figure 15

Trends in Percent of Facilities with Level A Violations



[Exhibit E to Amended Complaint]

1994 ILLINOIS DEPARTMENT OF PUBLIC HEALTH LONG-TERM CARE FACILITY STATEWIDE SUMMARY PROFILE

HEALTH SERVICE AREA
LTC PLANNING AREA
Illinois

TOTAL FACILITIES	1220
HOSPITAL-BASED UNITS	92
FREE-STANDING FACILITIES	1128
FACILITIES LICENSED FOR:	
NURSING CARE BEDS ONLY	776
SHELTERED CARE BEDS ONLY	51
DD CARE BEDS ONLY	301
FACILITIES BY OWNERSHIP TYPE	
GOVERNMENTAL	74
NON-PROFIT	522
FOR PROFIT	624

2. ADMISSION RESTRICTIONS

Aggressive Behavior	578
Chronic Alcoholism	692
Developmentally Disabled	533
Drug Addiction	805
Medicare Recipient	130
Medicaid Recipient	192
Mental Illness	683
Non-Ambulatory	156
Non-Mobile	202
Public Aid Recipient	125
Under 65 Years Old	67
Not Self-Medicating	164
DEVELOPMENTALLY DISABLED RESIDENTS PERMITTED UNDER BOGARD	1485

AVERAGE DAILY PAYMENT RATES

LEVEL OF CARE	SINGLE	DOUBLE
Skilled	117	100
Intermediate	90	78
Sheltered Care	61	49
Skilled Under 22	137	157
Intermediate DD	93	95

FACILITIES WITH:	
Public Payment Only	237
Life Care Residents Only	13

5. STAFFING PATTERNS

EMPLOYMENT CATEGORY	FULL-TIME	PART-TIME
Administrators	1404	149
Physicians	376	312
Director of Nursing	1066	33
Registered Nurses	6121	3407
LPNs	7226	2775
Certified Aides	30765	8457
Other Health Staff	4642	1290
Other Non-Health Staff	25280	8547
TOTAL STAFF	76880	24970

6. LONG-TERM CARE BEDS BY LEVEL OF CARE

LEVEL OF CARE	LICENSED BEDS	BEDS IN USE	MEDICARE CERTIFIED	MEDICAID CERTIFIED
Skilled	65960	39817	13779	10584
Intermediate	36976	51728		81158
Sheltered Care	7531	5570		
Skilled under 22	1157	945		0
Intermediate DD	7181	6842		8358
TOTAL BEDS	118805	104902	13779	100100

7. RESIDENTS BY AGE GROUP, SEX AND LEVEL OF CARE - DECEMBER 31, 1994

AGE GROUPS IN YEARS	SKILLED Male	SKILLED Female	INTERMEDIATE Male	INTERMEDIATE Female	SHELTERED Male	SHELTERED Female	UNDER AGE 22 Male	UNDER AGE 22 Female	INTERMED. DD Male	INTERMED. DD Female
Under 18	5	7	0	1	0	0	278	219	1	0
18 to 44	390	238	1858	1820	224	64	224	211	2116	1890
45 to 59	381	362	2138	1923	258	114	2	1	1000	848
60 to 64	282	291	1318	1518	90	72	0	0	195	161
65 to 74	1132	1601	3884	6042	170	281	0	0	254	181
75 to 84	1925	4300	5965	16037	345	1249	0	0	68	76
85 & Over	1495	5553	5255	24915	487	2203	0	0	0	9
TOTALS	5610	12352	20418	51456	1554	3983	504	431	3634	3165

8. RESIDENTS BY AGE GROUP, SEX AND PAYMENT SOURCE - DECEMBER 31, 1994

	MEDICARE Male	MEDICARE Female	MEDICAID Male	MEDICAID Female	OTHER PUBLIC Male	OTHER PUBLIC Female	INSURANCE Male	INSURANCE Female	PRIVATE PAY Male	PRIVATE PAY Female	TOTALS Male	TOTALS Female	TOTALS Total
Under 18	1	1	267	220	1	1	2	0	13	5	284	227	511
18 to 44	25	20	4386	3246	270	61	37	22	94	74	4812	3423	8235
45 to 59	58	30	3197	2889	246	95	55	53	211	181	3759	3248	7007
60 to 64	50	44	1510	1709	138	67	24	30	163	201	1885	2042	3927
65 to 74	436	385	3761	5725	298	158	86	86	859	1551	5440	8105	13545
75 to 84	767	1517	4556	11954	201	217	103	192	2677	7780	8304	21662	29966
85 & Over	467	1287	3255	16388	86	207	48	192	3381	14606	7237	32680	39917
TOTALS	1796	3484	20932	42124	1240	806	355	575	7398	24398	31721	71387	103108

9. RESIDENTS BY PAYMENT SOURCE AND LEVEL OF CARE

LEVEL OF CARE	MEDICARE	MEDICAID	OTHER PUBLIC	INSURANCE	PRIVATE PAY	TOTALS
Skilled	5283	6388	252	659	5394	17976
Intermediate		49078	853	264	21648	71863
Sheltered			921	6	4610	5537
Under Age 22		907	2	1	25	935
Intermed. DD		6683	18	0	98	6799
TOTALS	5283	63056	2046	930	31795	103110

10. RESIDENTS BY RACIAL/ETHNIC GROUP

RACIAL/ETHNIC GROUP	DD RESIDENTS	MI RESIDENTS	ALL OTHER RESIDENTS
White	7691	7441	74027
Black	1231	2317	7962
Asian	58	129	426
Hispanic	216	210	831
Other	30	52	487
TOTAL	9226	10149	83733

11. DD AND MI RESIDENTS BY SEX AND AGE GROUP

AGE GROUPS	DD Male	DD Female	MI Male	MI Female
Under 18	276	220	0	0
18 to 44	2517	2227	1520	757
45 to 59	1206	1049	1312	1115
60 to 64	258	249	533	565
65 to 74	392	359	801	1252
75 to 84	169	223	430	1119
85 & Over	27	54	140	594
TOTAL	4845	4381	4736	5400

12. ADMISSIONS AND DISCHARGES - 1994

A. Residents on January 1, 1994	102035
B. Total Admissions 1994	117379
C. Total Discharges 1994	116232
D. Residents on December 31, 1994	103196

13. PATIENT DAYS OF CARE - 1994 BY LEVEL OF CARE AND PATIENT TYPE

LEVEL OF CARE	DD	MI	OTHER	TOTAL	OCC
SNF	0	111204	6663579	6774783	84.2
ICF	455223	3164227	21227964	24847414	
SCR	89447	245773	1778710	2113930	76.9
SNF 22	341810			341810	80.9
ICF DD	2423427			2423427	92.5
TOTALS	3309907	3521204	29670253	36501364	

14. PATIENT DAYS BY PAYMENT SOURCE

MEDICARE	MEDICAID
1763016	2949861
	17237141
	299137
	2569916
1763016	22856055

15. RESIDENTS BY PRIMARY DIAGNOSIS

Neoplasms	2401
Endocrine/Metabolic	6133
Blood Disorders	1309
Mental Illness	10803
Developmental Disability	9062
Nervous System	8275
Circulatory System	24311
Respiratory System	4927
Digestive System	2886
Genito-Urinary System	1977
Skin Disorders	893
Muscule-Skeletal	6974
Injuries/Poisonings	3163
Other Medical	6462
Non-Medical Placement	877
TOTALS	90453

16. ALZHEIMER'S DISEASE PATIENTS - DECEMBER 31, 1994

A1. BY AGE GROUP

AGE GROUPS	MALE	FEMALE
Under 18	0	0
18 to 44	10	5
45 to 59	34	57
60 to 64	104	151
65 to 74	532	1039
75 to 84	1267	3846
85 & Over	947	4438
TOTALS	2894	9536

A2. BY RACIAL/ETHNIC GROUP

RACIAL/ETHNIC	RESIDENTS
White	11240
Black	1090
Asian	29
Hispanic	84
Other	80
TOTALS	12523

DEDICATED ALZHEIMER'S UNITS	113
DEDICATED ALZHEIMER'S BEDS	5052
DEDICATED ALZHEIMER'S MEDICARE BEDS	171

Source: Illinois Center for Health Statistics, Illinois Department of Public Health, 525 West Jefferson, Springfield, IL 62761 Telephone (217)-785-1064 September 1995